

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:
FINNEGAN, Alysia A.
MERCK & CO., INC.
126 EAST LINCOLN AVENUE
RAHWAY, NJ 07065-0907

PCT

WRITTEN OPINION

(PCT Rule 66)

Applicant's or agent's file reference		Date of Mailing (day/month/year)
PCT 20944Y		18 JAN 2005
International application No.	International filing date (day/month/year)	REPLY DUE within 1 months/days from the above date of mailing
PCT/US03/06437	03 March 2003 (03.03.2003)	05 March 2002 (05.03.2002)
International Patent Classification (IPC) or both national classification and IPC		
IPC(7): G01N 33/53, 33/566 and US Cl.: 435/7.1, 7.2		
Applicant		
MERCK & COMPANY, INC.		

1. This written opinion is the first (first, etc.) drawn by this International Preliminary Examining Authority.
2. This opinion contains indications relating to the following items:

- | | | |
|------|-------------------------------------|---|
| I | <input checked="" type="checkbox"/> | Basis of the opinion |
| II | <input type="checkbox"/> | Priority |
| III | <input type="checkbox"/> | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| IV | <input type="checkbox"/> | Lack of unity of invention |
| V | <input checked="" type="checkbox"/> | Reasoned statement under Rule 66.2 (a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| VI | <input type="checkbox"/> | Certain documents cited |
| VII | <input type="checkbox"/> | Certain defects in the international application |
| VIII | <input type="checkbox"/> | Certain observations on the international application |

3. The applicant is hereby invited to reply to this opinion.

When? See the time limit indicated above. ~~The applicant may, before the expiration of that time limit, request this Authority to grant an extension. See rule 66.2(d).~~

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.
For an informal communication with the examiner, see Rule 66.6

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 03 July 2004(03.07.2004)

Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer <i>Joseph F. Murphy</i> Joseph F. Murphy Telephone No. 571.272.1600
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Form PCT/IPEA/408 (cover sheet)(July 1998)

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WRITTEN OPINION

International application No.

PCT/US03/06437

I. Basis of the opinion

1. With regard to the **elements** of the international application:*

- ☒ the international application as originally filed
- ☒ the description:
 pages 1-24 _____, as originally filed
 pages NONE _____, filed with the demand
 pages NONE _____, filed with the letter of _____.
- ☒ the claims:
 pages 25-27 _____, as originally filed
 pages NONE _____, as amended (together with any statement) under Article 19
 pages NONE _____, filed with the demand
 pages NONE _____, filed with the letter of _____.
- ☒ the drawings:
 pages 1-8 _____, as originally filed
 pages NONE _____, filed with the demand
 pages NONE _____, filed with the letter of _____.
- ☐ the sequence listing part of the description:
 pages NONE _____, as originally filed
 pages NONE _____, filed with the demand
 pages NONE _____, filed with the letter of _____.

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the written opinion was drawn on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages NONE _____
- ☐ the claims, Nos. NONE _____
- ☐ the drawings, sheets/fig NONE _____

5. ☐ This opinion has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed."

WRITTEN OPINION

International application No.
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V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims <u>1-12</u>	YES
	Claims <u>NONE</u>	NO
Inventive Step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-12</u>	NO
Industrial Applicability (IA)	Claims <u>1-12</u>	YES
	Claims <u>NONE</u>	NO

2. CITATIONS AND EXPLANATIONS

Claims 1-12 lack an inventive step under PCT Article 33(3) as being obvious over Katsuki et al. (2001) in view of Shimokawa et al. (2002). The claims are drawn to a method of identifying compounds which can modulate the level of agouti related protein. The claims lack an inventive step because Katsuki teaches Obese men had significantly higher plasma concentrations of AGRP than nonobese men (showed that the circulating levels of AGRP are increased in obese men and that they are correlated with various parameters of obesity. Although correlation does not prove causation, the results of this study suggest that peripheral AGRP may play a role in the pathogenesis of obesity.

Shimokawa teaches the effects of C75 on the expression of key an orexigenic protein agouti-related protein (AgRP) neuropeptide messages in the hypothalami of lean and obese (ob/ob) mice. The suppressive effect of C75 on food intake in lean mice seems to be mediated both AgRP. Thus a method of identifying compounds which can modulate the level of agouti related protein lacks an inventive step.

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Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

TIME LIMIT:

The time limit set for response to a Written Opinion may not be extended. 37 CFR 1.484(d). Any response received after the expiration of the time limit set in the Written Opinion will not be considered in preparing the International Preliminary Examination Report.